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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/617,720

07/17/2000

Martin Nicklin

MSA-021.01

7893

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7590

09/14/2006

FOLEY HOAG, LLP

PATENT GROUP, WORLD TRADE CENTER WEST

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,720

Applicant(s)

NICKLIN ET AL.

Examiner

Fozia M. Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,27,28,30 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,27,28,30 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1a. Receipt of Applicants' arguments, filed on 27 June 2006 is acknowledged.

Status of Claims:

1b. Claims 12, 27-28, 30, 33-37 are pending and under consideration.

1c. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 101/112:

2a. Claims 12, 27-28, 30 and 33-37 stand rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, as set forth in the office actions mailed on 27 December 2005 and 13 April 2005.

Applicants argue that the instant specification, as filed, discloses that the claimed nucleic acids are useful in differentiating certain tissues types by detecting the level of expression of these specific nucleic acids in a biological sample. Applicants submit that the claimed IL-1 nucleic acid is highly expressed in placenta. Applicants contend that the asserted utility is specific and the skilled artisan would appreciate measuring the relative amount of a nucleic acid in a tissue as a real-world tool in areas such as histology and pathology. Applicants cite that high molecular weight cytokeratin (HMW CK) is routinely used to identify basal cells, while p63 is routinely used as a nuclear marker and cytokeratin 18 (CK18) is routinely used to identify epithelial cells in variety of tissue types.

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Applicants' arguments have been fully considered but are not deemed persuasive. The use of the claimed nucleic acids for tissue typing is not a specific utility, because the specification does not disclose that these nucleic acids are expressed in diseased tissues compared to normal tissues. The specification discloses that the claimed nucleic acids are expressed in placenta, however, the specification fails to disclose the significance of said expression. Applicants are correct in that cytokeratins are routinely used to identify basal cells or epithelial cells. It is known in the art that basal specific cytokeratin antibody (34 β E12) and the basal cell specific nuclear marker P63 are negative stains to confirm malignancy. These markers are very useful for demonstration of basal cells, as the presence of basal cells argues against a diagnosis of invasive prostate carcinoma. Thus, the cytokeratins are negative markers to confirm malignancy. For example, Shah et al, (the American Journal of Surgical Pathology. 2002, Vol. 26, No.9, pages 1168-1168, especially page 1162, column 1), tested 51 prostate carcinoma cases of prostate needle biopsies, (NBX) and demonstrated that none of the 51 cases stained positive for either P63 or 34 β E12 antibody, (see page 1167, column 1). Thus, these cytokeratin basal markers are diagnostic tools for prostate carcinoma. In the instant application, Applicants have not shown that the claimed nucleic acids are negative or positive diagnostic markers for any disorder or disease condition. Accordingly, the fact that the claimed nucleic acid is expressed in placenta, does not afford the claimed invention a specific and substantial asserted utility or a well-established utility.

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2b. Claims 12, 27-28, 30 and 33-37 are also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The skilled artisan would not be able to use the claimed invention, because the significance of the claimed nucleic acid's expression in placenta is not disclosed. The specification fails to establish a link between said nucleic acid and a physiological condition.

Conclusion:

3. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-


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0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
04 September 2006


EILEEN B. O'HARA
PRIMARY EXAMINER